

PTO/SB/08A (08-03)

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Substitute for form 1449/PTO

## INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Use as many sheets as necessary)

Sheet

1

of 2

### Complete if Known

Application Number	10/616,776
Filing Date	July 10, 2003
First Named Inventor	Craig Heacock
Art Unit	Not Yet Known
Examiner Name	Not Yet Known
Attorney Docket Number	CP241

U. S. PATENT DOCUMENTS					
Examiner Initials*	Cite No. <sup>1</sup>	Document Number	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number-Kind Code <sup>2</sup> (if known)			
SHA	A1	US- RE37,516 E	01-15-2002	Grebow et al.	
SHA	A2	US- 4,177,290	12-04-1979	Lafon	
SHA	A3	US- 4,927,855	05-22-1990	Lafon	
SHA	A4	US- 5,180,745	01-19-1993	Lafon	
SHA	A5	US- 5,391,576	02-21-1995	Lafon, deceased	
SHA	A6	US- 5,612,379	03-18-1997	Laurent	
SHA	A7	US- 5,719,168	02-17-1998	Laurent	
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SHA	A12	US- 6,488,164 B2	12-03-2002	Miller et al.	
		US-			

### FOREIGN PATENT DOCUMENTS

Examiner Initials*	Cite No. <sup>1</sup>	Foreign Patent Document	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages Or Relevant Figures Appear	T <sup>6</sup>
		Country Code <sup>3</sup> -Number <sup>4</sup> -Kind Code <sup>5</sup> (if known)				
SHA	B1	EP 547 952 B1	09-06-1995	Lafon		
SHA	B2	EP 594 507 A1	04/27/94	Laurent		
SHA	B3	WO 02/096401 A1	12-05-2002	Corvari et al.		

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19 JANUARY 2006

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<b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b>  <i>(Use as many sheets as necessary)</i>				Application Number	10/616,776
				Filing Date	July 10, 2003
				First Named Inventor	Craig Heacock
				Art Unit	Not Yet Known
				Examiner Name	Not Yet Known
Sheet	2	of	2	Attorney Docket Number	CP241

NON PATENT LITERATURE DOCUMENTS						
Examiner Initials*	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.				T <sup>2</sup>
<i>Sh</i>	01	Duteil et al., European Journal of Pharmacology, 1990, 180, 49-58				
<i>Sh</i>	02	Saletu B. et al., Int. J. Clin Pharm. Res., 1989, IX(3), 183-195				
<i>Sh</i>	03	Bastuji et al., Prog. Neuro-Psychopharmacol & Biol. Psychiat., 1988, 12, 695-700				

Examiner Signature	<i>Sh</i>	Date Considered	19 JANUARY 2006
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## **INFORMATION DISCLOSURE STATEMENT BY APPLICANT**

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**Complete if Known**

Application Number	10/616,776
Filing Date	July 10, 2003
First Named Inventor	Craig Heacock et al.
Art Unit	1614
Examiner Name	Not Yet Known
Attorney Docket Number	CP241

U. S. PATENT DOCUMENTS

## FOREIGN PATENT DOCUMENTS

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		Country Code <sup>2</sup> Number <sup>4</sup> Kind Code <sup>5</sup> (if known)			
SHL	B4	WO 00/37055	06-29-00	Qui et al.	

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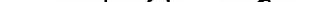
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				Application Number	10/616,776
				Filing Date	July 10, 2003
				First Named Inventor	Craig Heacock et al.
				Art Unit	1614
				Examiner Name	Not Yet Known
Sheet	2	of	2	Attorney Docket Number	CP241

## NON-PATENT LITERATURE DOCUMENTS

Examiner Signature		Date Considered	19 JANUARY 2006
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<p><b>Form PTO-1449 Modified</b></p> <p>List of Patent and Publications Cited by Applicant (Use several sheets if necessary)</p> <p>U.S. Department of Commerce Patent and Trademark Office</p>	Docket No. CEPH-2249/ CP241	Application No. 10/616,776
	Applicant Craig Heacock, et al.	
	Filing Date July 10, 2003	Group 1615
	Confirmation No. 1994	

**OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)**

Ha	21	Becue T. et al., "Confirmation of the Structure of By-Products in the Synthesis of Modafinil by Liquid Chromatography-Mass Spectrometry," <i>J. of Chromatography</i> , 1991, 557, 489-494
Ha	22	Carlson, R.F., et al., "Efficacy and safety of reformulated, micronized glyburide tablets in patients with non-insulin-dependent diabetes mellitus: a multicenter, double-blind randomized trial," <i>Clin Ther</i> , 1993, 15(5), 788-796
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Ha	26	FDA/CDER guidance document "Dissolution Testing of Immediate Release Solid Oral Dosage Forms," 1997, 1-11, A-1 – A-2
Ha	27	FDA/CDER guidance document "Immediate Release Solid Dosage Forms: Scale-up and Post Approval Changes (SUPAC-IR): Chemistry, Manufacturing and Controls, In Vitro Dissolution Testing and In Vivo Bioequivalence Documentation," 1995, 1-26, A1
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**EXAMINER** HASAN S. AHMED

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**OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)**

<i>Ha</i>	31	Hörter D., et al., "Influence of Physicochemical Properties On Dissolution Of Drugs In The Gastrointestinal Tract," <i>Adv Drug Deliv Rev</i> , 2001, 46(1-3), 75-87
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<i>Ha</i>	33	Kondo, N., et al., "Pharmacokinetics of a micronized, poorly water-soluble drug, HO-221, in experimental animals," <i>Biol Pharm Bull</i> , 1993, 16(8), 746-800
<i>Ha</i>	34	Lauharanta, J., et al., "Pharmacokinetics of 8-methoxysoralen in serum and suction blister fluid," <i>Arch Dermatol Res</i> , 1982, 273(1/2), 111-114
<i>Ha</i>	35	Lyons T.J. et al., "Modafinil: The Unique Properties of a New Stimulant," <i>Aviation, Space &amp; Environ Med</i> , 1991, 432-435
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**OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)**

41	Remington's Pharmaceutical Sciences, 16 <sup>th</sup> Ed., 1980, 305-306
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43	Roze C., et al., "Drug CRL 40 028-Induced Inhibition of Pancreatic Secretion in Rats," <i>Arch Int Pharmacodyn</i> , 1983, 265, 119-127
44	Shah V.P. et al., "In Vitro Dissolution Profile Comparison – Statistics and Analysis of the Similarity Factor, $f_2$ ," <i>Pharmaceutical Research</i> , 1998, 15(6), 889-896
45	Sheperd, J., "The fibrates in clinical practice: focus on micronised fenofibrate," <i>Atherosclerosis</i> , 1994, 110(Suppl), S55-S63
46	Stolk, L.M.L., et al., "Comparison of bioavailability and phototoxicity of two oral preparations of 5-methoxysoralen," <i>British J. of Dermatology</i> , 1985, 112, 469-473
47	Treffel, P., et al., "A new micronized 5-methoxysoralen preparation," <i>Acta Derm Venerol</i> , 1992, 72, 65-67
48	Wadke D.A., et al., "Preformulation testing," <i>Pharmaceutical Dosage Forms: Tablets</i> , 2 <sup>nd</sup> Ed., 1989, 1-73
49	Wilson et al., Textbook of Organic Medicinal and Pharmaceutical Chemistry, 6 <sup>th</sup> Ed., <i>J.B. Lippincott Company</i> , 1971, 386-387

EXAMINER HASAN S. AHMED

DATE CONSIDERED 19 JANUARY 2006

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U.S. Department of Commerce Patent and Trademark Office		Filing Date July 10, 2003	Group 1615
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**U. S. PATENT DOCUMENTS**

Examiner Initial		Document No.	Date	Name	Class	Subclass
<i>Ha</i>	50	4,002,718	01/11/77	Gardella et al.	424	37
<i>Ha</i>	51	4,122,157	10/24/78	Huber	424	21
<i>Ha</i>	52	4,196,188	04/01/80	Besins	424	37
<i>Ha</i>	53	4,332,721	06/01/82	Bernini	260	239.57
<i>Ha</i>	54	4,517,179	05/14/85	Raghunathan	514	249
<i>Ha</i>	55	4,713,246	12/15/87	Begum et al.	424	455
<i>Ha</i>	56	4,880,623	11/14/89	Piergiorgio et al.	424	465
<i>Ha</i>	57	4,895,726	01/23/90	Curtet et al.	424	456
<i>Ha</i>	58	5,021,242	06/04/91	Romer et al.	424	436
<i>Ha</i>	59	5,202,129	04/13/93	Samejima et al.	424	489
<i>Ha</i>	60	5,618,845	04/08/97	Grebow et al.	514	618
<i>Ha</i>	61	2004/0167255	08/26/04	Lee et al.	524	100
<i>Ha</i>	62	2004/0105891	06/03/04	Bentolila et al.	424	489

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<b>OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)</b>			
<i>Sh</i>	72	Provigil® (modafinil) – FDA Approved Drafting Labeling, NDA 20-717, <a href="http://www.fda.gov/cder/foi/label/1998/20717lbl.pdf">http://www.fda.gov/cder/foi/label/1998/20717lbl.pdf</a> , 1998, 1-28	
<b>EXAMINER</b> <i>Hasan S. Ahmed</i>		<b>DATE CONSIDERED</b> <i>19 JANUARY 2006</i>	

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<i>Ha</i>	73	4,329,363	05/11/82	Dorn, et al.	424	320
<i>Ha</i>	74	5,281,607	01/25/94	Stone, et al.	514	280
<i>Ha</i>	75	5,401,776	03/28/95	Laurent	514	618
<i>Ha</i>	76	2004/0167225 A1	08/26/04	Singh, et al.	514	618

**FOREIGN PATENT DOCUMENTS**

Examiner Initial		Document No.	Date	Country	Translation	
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